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Commercial and Improvised Pelvic Compression Devices

Applied Force and Implications for Hemorrhage Control

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ABSTRACT

Uncontrolled hemorrhage secondary to unstable pelvic fractures is a preventable cause of prehospital death in the military and civilian sectors. Because the mortality rate associated with unstable pelvic ring injuries exceeds 50%, the use of external compression devices for associated hemorrhage control is paramount. During mass casualty incidents and in austere settings, the need for multiple external compression devices may arise. In assessing the efficacy of these devices, the magnitude of applied force has been offered as a surrogate measure of pubic symphysis diastasis reduction and subsequent hemostasis. This study offers a sensor-circuit assessment of applied force for a convenience sample of pelvic compression devices. The SAM® (structural aluminum malleable) Pelvic Sling II (SAM Medical) and improvised compression devices, including a SAM Splint tightened by a Combat Application Tourniquet® (C-A-T; North American Rescue) and a SAM® Splint tightened by a cravat, as well as two joined cravats and a standard-issue military belt, were assessed in male and female subjects. As hypothesized, compressive forces applied to the pelvis did not vary significantly based on device operator, subject sex, and subject body fat percentage. The use of the military belt as an improvised method to obtain pelvic stabilization is not advised.

Keywords: pelvic ring fractures; pelvic injuries; commercial pelvic compression devices; improvised pelvic compression devices; mass casualty incidents

Introduction

Blast injuries are the most common cause of pelvic fractures among military members. 1,2 Data from Operations Iraqi and Enduring Freedom identify anterior compression injuries as associated with a 48% mortality rate. 3,4 Each year, nearly 120,000 civilians experience pelvic ring injuries as a result of motor vehicle accidents or falls. 5-7 Historically, mortality rates as high as 54% have been reported in this population. 5,7-13 In the setting of severe pelvic ring injury, massive hemorrhage occurs secondary to bone extravasation, vascular disruption, and an increase in pelvic volume. 9,10,12 An unstable pelvic fracture (e.g., open book, vertical shear injury) is difficult to

identify on clinical examination.¹⁴ Current military Tactical Combat Casualty Care guidelines direct the application of a pelvic compression device to all patients who experience severe blast or blunt traumatic injury and exhibit one or more of the following: pelvic pain, unconsciousness, shock, major lower extremity amputation or near amputation, or examination results suggestive of pelvic injury.¹⁴ Similarly, Tactical Emergency Casualty Care guidelines advocate the use of pelvic binding techniques during the provision of care in the warm zone (i.e., indirect threat),¹⁵ and Advanced Trauma Life Support guidelines recommend pelvic stabilization for hemodynamically unstable patients with mechanisms suggestive of pelvic injury.^{5,16,17}

Early pelvic stabilization has been shown to improve mean arterial blood pressure,18 decrease blood transfusion requirements, 9,19,20 decrease length of stay in intensive care units, and shorten duration of hospital stay. 19-21 Numerous hospital-based studies have identified commercial compression devices (i.e., the SAM® Pelvic Sling II, the T-PODCombat™ Pelvic Stabilization Device [Pyng Medical]) as capable of effectively reducing and stabilizing pelvic ring injuries; 16-18,21 therefore, the prehospital application of external pelvic compression may be life-saving. For military members serving in austere environments or personnel responding to mass casualty incidents, access to commercial pelvic compression devices may be limited. We sought to assess the magnitude of force applied to the pelvis at the level of the greater trochanters, following the application of a convenience sample of commercial and improvised external compression devices to male and female subjects.

To the best of our knowledge, this is the first study to evaluate compressive forces applied by improvised pelvic compression devices at the greater trochanters. There are no published data regarding a minimum compressive force necessary to reduce the symphysis diastasis. Identifying a threshold force required to reduce an unstable pelvis would identify improvised devices as acceptable for use. We hypothesized that the applied force for all devices would not vary significantly, based on device operator, subject sex, or body fat percentage, and that the SAM Pelvic Sling II would apply the greatest force to the pelvis.

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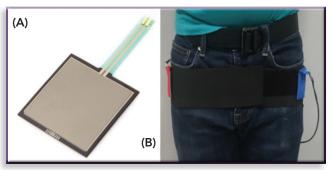
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Methods

Commercially purchased force-sensitive resistors (FSRs) (FSR Model 406; Interlink Electronics; Food and Drug Administration approved) were calibrated and used for force assessments (Figure 1A). In a closed circuit, the application of force to an FSR results in variation in resistance values, altering the voltage of the circuit, and ultimately allowing for force magnitude determination. A specialized belt with Velcro attachments was designed for FSR application, allowing for adjustment to a respective subject's greater trochanters (Figure 1B). An Adafruit Feather M0 Adalogger microcontroller (manufacturer part number 2798; Adafruit Industries; Food and Drug Administration approved) was used for data collection. Researchers participated in a formal training session regarding compression device application. All pelvic-compression devices were placed and secured atop the FSR belt.

FIGURE 1 (A) Force-sensitive resistor (FSR); (B) FSR belt with Velcro attachments.



This study was approved by Wright State University's Institutional Review Board (protocol #06586). Subjects were enrolled on a volunteer basis. Greater trochanter circumference exceeding 115 cm (45 in) precludes proper closure and tightening of the belt; therefore, individuals possessing this anatomic variant were excluded from the study. In total, 13 males and 17 females participated. After informed consent was obtained, each subject was asked to recline on a soft mat. A researcher then placed the force-sensor system on the subject. A pelvic compression device was applied to the subjects' greater trochanters so that objective force data could be collected over a 3-minute interval

at a sample rate of 4 Hz. Each device was tightened as much as possible. Four researchers shared the responsibility of applying the five pelvic compression devices to each subject.

Descriptions of Compression Devices and Their Applications

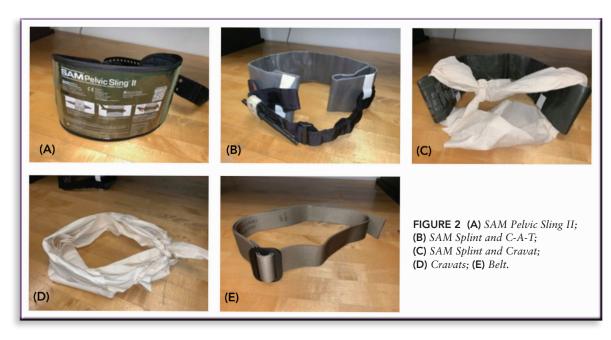
SAM Pelvic Sling II. Marketed by SAM Medical, the Pelvic Sling II is a force-controlled circumferential pelvic belt with SAM AUTOSTOP technology, which alerts the user with a tactile and audible "click" to avoiding overtightening²² (Figure 2A). Researchers centered the device anatomically at a subject's greater trochanters and tightened until the AUTOSTOP engaged (Figure 2A).

SAM Splint and C-A-T. The C-A-T uses a windlass system with a free-moving internal band to provide circumferential pressure.²³ Researchers connected two tourniquets together using the buckle, opened the SAM Splint to length, and taped the double-tourniquet to the SAM Splint. The SAM Splint was then placed under the study subject, in line with the greater trochanters, secured with the tourniquet buckle, and tightened as much as possible with the tourniquet windlass (Figure 2B).

SAM Splint and Cravat®. The SAM splint is a soft aluminum strip encased in a polyethylene closed-cell foam coating, designed to be a compact, lightweight device for the immobilization of bone and stabilization of soft-tissue injuries.²⁴ Researchers opened the SAM Splint to length, folded a portion of each end, and secured the ends with medical tape, thereby creating keyholes. They then placed the SAM Splint under the study subject, in line with the greater trochanters, and secured it by lacing a cravat through the keyholes, tying it with as much tension as possible (Figure 2C).

Cravats. Researchers joined two cravats (triangular muslin bandages measuring 37 inches by 37 inches by 52 inches)²⁵ and tied them around a subject's greater trochanters, applying as much tension as possible (Figure 2D).

Belt. Researchers placed a military belt at the subject's greater trochanters and tightened it with as much tension as possible (Figure 2E).

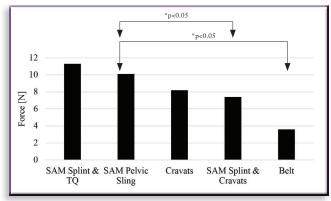


Results

All statistical tests were performed using JMP statistical software with a significance level of $\alpha = 0.05$. We analyzed force differences between the left and right FSRs on each subjects' greater trochanters. A one-way ANOVA revealed no significant differences between the left and right force values. Thus, each subject's left and right force values were averaged for the remaining data analysis. While the team was able to analyze the effect of different subject qualities (e.g., sex and body fat percentage) on the force applied at the greater trochanters, it was also important to determine whether force readings varied based on device application by individual researchers. For all compression devices, there was no significant difference (p =.0728) identified among the researchers when comparing resulting force applied to subjects' greater trochanters.

Our initial hypothesis was that the commercial SAM Pelvic Sling would apply greater force to the pelvis than the improvised pelvic compression devices would. Therefore, we used Student's t-test to compare the greater trochanter force measurements of the improvised devices with those of the SAM Pelvic Sling (Figure 3). Interestingly, the magnitude of applied force of the SAM Splint and tourniquet was the greatest of all devices; however, this was not statistically significant compared with the SAM Pelvic Sling. As detailed in Figure 3, the belt exhibited significantly lower force characteristics (p = .0044) compared with the SAM Pelvic Sling. Additionally, the SAM Splint and cravats were found to have a lower compressive force than the SAM Pelvic Sling. The SAM Splint and tourniquet, and the cravats, did not demonstrate significant differences compared with the SAM Pelvic Sling (p = .3728).

FIGURE 3 Average comparison of compressive force by device.



TO = tourniquet.

Next, we analyzed the force characteristics for each device based on the subjects' sex. The goal was to determine whether there was a trend in force characteristics because the team hypothesized that there would be no difference in applied forces between the two sexes. As seen in Figure 4, applied force readings from female subjects were greater than those of male subjects; however, this was not statistically significant (p = .1323).

Supporting our hypothesis, additional data analysis revealed no strong correlation between body fat percentage and applied pelvic compression device forces for male and female subjects (Table 1).

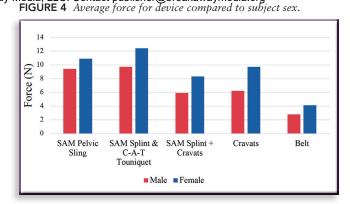


TABLE 1 Force versus Body Fat Percentage for All Devices

	Male		Female	
Devices	r	r ²	r	r ²
SAM Pelvic Sling II	-0.07	0.0049	-0.224277	0.0503
SAM Splint and C-A-T	-0.428135	0.1833	0.1621727	0.0263
SAM Splint and Cravat	-0.368646	0.1359	-0.014142	0.0002
Cravat	-0.294958	0.087	0.0479583	0.0023
Belt	-0.096437	0.0093	0.1264911	0.016

Discussion

Bottlang et al.²⁶ laid the foundation for pelvic compression device research with their 2002 cadaveric study (N = 7; 4 males, 3 females), which assessed external pelvic compression device strap placement, force application, and computed tomography (CT)-verified pubic symphysis diastasis reduction in stable and unstable pelvic fractures. According to the authors, when a prototype 50mm rubber strap was placed at the level of the greater trochanters, an applied force of 180 ± 50 Newtons (N), as determined by sensors integrated into the strap, effectively reduced unstable pelvic fractures without causing significant internal rotation of lateral compression fractures. Bottlang et al.²⁶ measured the tensile force required to reduce the pubic diaphysis as visualized by CT. In contrast, our sensor system assessed the direct normal compressive force applied to the greater trochanters by the applied devices. This measurement allowed us to acquire data and draw comparisons.

We initially hypothesized that the SAM Pelvic Sling would generate the greatest pelvic compressive force; however, our trials identified the SAM Splint and tourniquet, and the cravats, as producing forces comparable to those of the SAM® Pelvic Sling. We believe that this may be secondary to the SAM Pelvic Sling's AUTOSTOP technology—alerting the end user to discontinue applying force when 150 N have been attained. In contrast, the SAM Splint and tourniquet, and the cravats, were tightened to the greatest extent possible. Of all the devices accessed, the standard-issue military belt was found to have the smallest magnitude of applied force.

Although this study examined compressive force, other factors may be considered when selecting a device for use in tactical environments, such as material availability, component size and weight, and assembly time. For example, the SAM Pelvic Sling is currently issued to Air Force Pararescuemen for external pelvic compression; however, given its size, it is infrequently carried in service members' individual rucksacks. The ability to improvise a device, both in the military and civilian sectors, may be vital during mass casualty events, where

^{*}statistically significant

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multiple patients may require rapid stabilization and the supply of commercial devices may quickly be depleted.

The effect of the improvised compression device material on diagnostic imaging is of some importance. Removal or replacement of the device prior to imaging, or obscuration of images, may delay patient care. Commercial devices are compatible with radiographs and CT. Although the SAM Splint was designed with an aluminum core, the low effective atomic number of this metal makes it less prone to producing scatter in CT scans.27

Limitations

This study examined the compressive force generated by pelvic compression devices in healthy volunteers. Pain was not assessed as a limitation of compression device application; however, given that applied forces did not vary significantly in the application of the compressive devices between researchers, we do not suspect that this served as a significant confounding factor. A convenience sample of study subjects aged 18 to 48 years were recruited to participate. The average body fat percentage for males was 26.5% and for females, 25.2%. Although there are limited studies detailing body fat percentages among military members, current estimates identify male and female Army service members, aged 18 to 53 years, as possessing a body fat percentage of $26.7 \pm 3.8\%$ and $40.3 \pm$ 3.7%, respectively.²⁸ Therefore, we believe that our sample is reflective of male members of the current military population. Additional studies are required in the female population. The SAM® Splint and C-A-T are FDA-approved devices. Applications previously described constitute off-label uses.

Conclusions

In our study of 30 participants (13 males, 17 females), the SAM Splint and tourniquet device performed well, and thus may be an improvised device option when time and tactics permit. Otherwise, two cravats tied together may apply a similar force to the pelvis as that of the commercial SAM Pelvic Sling. Application of cravats to the traumatized pelvis is a simple procedure using lightweight, compact, and inexpensive materials that are easily removed for assessment and do not affect diagnostic imaging. All applied forces were assessed while subjects remained motionless; future work should examine the effect of patient transfer on force characteristics. At this time, we do not recommend the use of a military belt as an improvised pelvic compression device.

Author Contributions

SR conceived the study concept. AK recruited a student engineering team. RB enrolled study participants. RB, DP, LB, CG, and RS performed study trials and collected data. DP analyzed the data. ES and AK wrote the study manuscript. All authors read and approved the study manuscript.

Conflict of Interest Statement

The authors have no conflicts of interest to report.

Financial Disclosure

The authors have no financial relationships relevant to this article to disclose.

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